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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-491,322	01/25/2000	Mich B. Hem	TSRI 184.2D1	8393

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FOLEY & LARDNER

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/06/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/491,322

Applicant(s)

HEIN ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 15-27,29-65 and 83-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-27,29-65 and 83-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 24.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment After Final Rejection, filed August 11, 2003, has been entered.

Claims 1-12, 13-14, 28 and 66-82 are cancelled.

Claims 15, 17-20, 23-27, 29-34 and 39-41 are currently amended.

Claim 92 is newly added.

Claims 15-27, 29-65 and 83-92 are pending and are examined.

The finality of the office action mailed May 19, 2003 is withdrawn.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 92, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 92 is indefinite in the recitation of "said nucleotide sequences also encodes" in line 7. First, "said nucleotide sequences" lacks antecedent basis in the claim, as the claim recites in line 6 that the plant cells contain "nucleotide sequence" in the singular. Second, in the recitation of "said nucleotide sequences also encodes" in line 7, the verb encode (encodes) does not agree with the subject (nucleotide sequences). Third, the Examiner notes that independent claims 41 and 83 are both directed to plant cells containing "nucleotides sequences" in the plural, which suggests that Applicant may have intended that claim 92 also be directed to plant cells containing "nucleotides sequences" in the plural. It is

Art Unit: 1638

suggested that claim 92 be amended to indicate whether the plant cells contain one, or more than one, nucleotide sequence encoding the immunoglobulin heavy and light chain polypeptides.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-27, 29-65 and 83-92 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,417,429 (Hein et al., July 9, 2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this

Art Unit: 1638

rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-69 of U.S. Patent No. 6,417,429 are directed to transgenic plants that express immunoglobulins and methods of making said plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 6,417,429.

Claims 15-27, 29-65 and 83-92 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,303,341 (Hiatt et al., October 16, 2001).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference

Art Unit: 1638

under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-53 of U.S. Patent No. 6,303,341 are directed to immunoglobulins made in plants, compositions comprising immunoglobulins made in plants, and methods of making immunoglobulins by extracting them from transgenic plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 6,303,341.

Claims 15-27, 29-65 and 83-92 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,046,037 (Hiatt et al. April 4, 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C.

Art Unit: 1638

102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-24 of U.S. Patent No. 6,046,037 are directed to transgenic plant cells that express immunoglobulins. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 6,046,037.

Claims 15-27, 29-65 and 83-92 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,639,947 (Hiatt et al., June 17, 1997).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-11 of U.S. Patent No. 5,639,947 are directed to transgenic plants that express immunoglobulins and methods of making said plants. The conflicting claims are not patentably distinct from each other

Art Unit: 1638

because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 5,639,947.

Claims 15-27, 29-65 and 83-92 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,202,422 (Hiatt et al., April 13, 1993).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Art Unit: 1638

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-5 of U.S. Patent No. 5,202,422 are directed to immunoglobulins made in plants and compositions comprising immunoglobulins made in plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 5,202,422.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-27, 29-65 and 83-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,959,177 (Hein et al., September 28, 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins

Art Unit: 1638

made in plants, whereas claims 1-12 of U.S. Patent No. 5,959,177 are directed to transgenic plants that express secretory immunoglobulins and methods of making secretory immunoglobulins using said plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 5,959,177.

Claims 15-27, 29-65 and 83-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of U.S. Patent No. 6,417,429 (Hein et al., July 9, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-69 of U.S. Patent No. 6,417,429 are directed to transgenic plants that express immunoglobulins and methods of making said plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 6,417,429.

Claims 15-27, 29-65 and 83-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,303,341 (Hiatt et al., October 16, 2001). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant

Art Unit: 1638

application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-53 of U.S. Patent No. 6,303,341 are directed to immunoglobulins made in plants, compositions comprising immunoglobulins made in plants, and methods of making immunoglobulins by extracting them from transgenic plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 6,303,341.

Claims 15-27, 29-65 and 83-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,046,037 (Hiatt et al., April 4, 2000). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-24 of U.S. Patent No. 6,046,037 are directed to transgenic plant cells that express immunoglobulins. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 6,046,037.

Claims 15-27, 29-65 and 83-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,639,947 (Hiatt et al., June 17, 1997). Although the conflicting claims are not identical, they

Art Unit: 1638

are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-11 of U.S. Patent No. 5,639,947 are directed to transgenic plants that express immunoglobulins and methods of making said plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 5,639,947.

Claims 15-27, 29-65 and 83-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,202,422 (Hiatt et al., April 13, 1993). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-27, 29-65 and 83-92 of the instant application are directed to methods of passive immunization using immunoglobulins made in plants, whereas claims 1-5 of U.S. Patent No. 5,202,422 are directed to immunoglobulins made in plants and compositions comprising immunoglobulins made in plants. The conflicting claims are not patentably distinct from each other because the use of immunoglobulins for the purpose of passive immunization was well established in the art prior to the effective filing dates of both the instant application and U.S. Patent No. 5,202,422.

Remarks

No claim is allowed.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600